EFFICACY REVIEW

Product: **Bromadiolone Bait Pellets, Bromadiolone 2.5% Concentrate, and Bromadiolone Bromadiolone Technical**

Date: September 16, 2003

EPA File Symbol(s): 63823-LR, 63823-LG, 63823-LN

DP Bar code(s): D287387, D287420, and D287408

Chemical Code: 112001 Bromadiolone

Formulation(s): Bromadiolone Baits (Pellets), a 99% Bromadiolone Technical, and a 2.5% Bromadiolone Concentrate.

Purpose for Review: The purpose for this review is to determine if the Bromadiolone Pelleted Baits and the asscoiated 2.5% Bromadiolone Concentrate are efficacious as a rat or mouse control product.

MRID(s): **45810709** J. Baroch. 2002. Norway Rat (*Rattus norvegicus*) Acute Dry Bait Laboratory Test Using LX-125 Bromadiolone Bait Pellets, Formula Number 403: One-Day Test. Genesis Laboratories, lnc. Unpublished Report. Study #01030. 89pp.

45810710 J. Baroch. 2002. Norway Rat (*Rattus norvegicus*) Anticoagulant Dry Bait Laboratory Test Using LX-125 Bromadiolone Bait Pellets, Formula Number 403: Three-Day Test. Genesis Laboratories, Inc. Unpublished Report. Study #01031. 87pp.

45810711 J. Baroch. 2002. House Mouse (*Mus musculus*) Acute Dry Bait Laboratory Test Using LX-125 Bromadiolone Bait Pellets, Formula Number 403: One-Day Test. Genesis Laboratories, Inc. Unpublished Report. Study #01032. 73pp.

45810712 J. Baroch. 2002. House Mouse (*Mus musculus*) Anticoagulant Dry Bait Laboratory Test Using LX-125 Bromadiolone Bait Pellets, Formula Number 403: Three-Day Test. Genesis Laboratories, Inc. Unpublished Report. Study #01033. 77pp.

Good Laboratory Practices: Yes

Branch Supervisor: Meredith Laws, Branch Chief

Team Reviewer: John Hebert, Product Manager -PM Team 04

IRB Reviewer: Geraldine R. McCann, Environmental Protection Specialist

BACKGROUND: **Landis International** has applied for a new product registration for Bromadiolone Bait Pellets, a Bromadiolone Technical, and a Concentrate to control rats and mice. The efficacy tests associated with these products were conducted according to the Product Performance guidelines 96-10: Commensal Rodenticides: OPP Designation 1.209: Norway Rat/Roof Rat Acute Dry Bait Laboratory Test Method; OPP Designation: 1.203: Standard Norway Rat Anitcoagulant Dry Bait Laboratory Test; OPP Designation 1.210: Standard House Mouse Acute Dry Bait Laboratory Test Method, and OPP Designation: 1.204: Standard House Mouse Acute Dry Bait Laboratory Test Method, respectfully. This is a review of the four efficacy tests and the pelleted bait label.

REVIEW OF DATA:

1. **45810709** J. Baroch. 2002. Norway Rat (*Rattus norvegicus*) Acute Dry Bait Laboratory Test Using LX-125 Bromadiolone Bait Pellets, Formula Number 403: One-Day Test. Genesis Laboratories, Inc. Unpublished Report. Study #01030. 89pp.

DISCUSSION: This study was conducted to determine the efficacy of a pelleted bait formulated (0.005% bromadiolone) for control of male and female Wistar albino rats from Harlan Sprague Dawley, Inc. in Indianapolis, Indiana, in a one-day feeding test.

Rats arrived at the test facility October 22, 2001. The testing began November 1, 2001. The test was structured to fit the "single-feeding" test of the OPP guideline 1.209. The rats were presented with 85 g of the pelleted bait for one day. The test lasted 10 days. Three males survived: two from Replicate I (61 and 63) and one in Replicate II (75). No control animals died.

The difference between the average pretest weights for the male and female rats should be within 50 grams and the average difference in the weights pretest was 1.6 grams.

In Appendix D7, Test Substance Accountability (page 84), the bromadiolone bait was formulated at Genesis Laboratory on October 11, 2001, and pelletized at Uniscope, Inc. Johnstown, Colorado, on October 12, 2001. The Genesis Laboratory log number was recorded as a reference number to the bait ("01-TS-38"). The OPP rat and mouse challenge diet formulation is referenced as an SOP.

Bait acceptance for the two treated groups combined was 45.8%. The label specifies 128 g (3 packets) to 425 g (10 packets) be placed uninterrupted for 10 days. When testing a particular product, the application rate stated on the label should be the application tested.

Paper plates were placed beneath the feeding area of the rats to catch any spilled bait or challenge diet. There was no discussion about weighing back the spillage, just that it was figured into the equation. Since this was a 1-day test, there would not be any issues surrounding reissuing the dishes back to the animals. The use of

glass feeders is also questionable since the guidelines call for metal or ceramic feeders designed so that rats may not nestle or wallow in the diet. A stainless steel automatic watering system was used instead of the gravity fed or open cup waterers as specified in OPP guideline 1.209, 6.2.

The guidelines for the test facility specify the temperature should range from 20 to 25 °C and the humidity should be between 50 and 55 % (OPP guideline 1.209, 5.1). The temperature for this test. ranged from 19 to 26 °C pre-test and 18 to 26 °C during the test. The humidity ranged from 32 to 74 % pre-test and 24 to 71% during the test period. More consistency should be sought when conducting these laboratory tests.

Mortality of the test animals was 92.5 %. Results of the rat test are summarized below:

Table 1. Rep I - Rats on Pelleted Bromadiolone Bait

Pretest Weights **Bait I-Day Test-Consumption and Mortality**

Sex	Average Group Weight (g)	OPP Diet Consumed (g)	Treated Bait Consumed (g)	Total Bait Consumption (g)
M (10)	232.61	289.4	290.7	580.1
F (10)	228.17	**90% Mortality**		Percent **Bromadiolone Bait** Consumed **50 %**
Total (20)	Group Difference 4.44			

Table 2. Rep II - Rats on Pelleted Bromadiolone

Pretest Weights **Bait 1-Day Test-Consumption and Mortality**

Sex	Average Group Weight (g)	OPP Diet Consumed (g)	Treated Bait Consumed (g)	Total Bait Consumption (g)
M (10)	230.31	329.5	233	562.5
F (10)	227.69	**95% Mortality**		Percent **Bromadiolone Bait** Consumed **41.4%**
Total (20)	Group Difference 2.62			

Table 3. Test III-Rats on OPP Challenge Diet Bait 1-Day Pretest Weights Test-Consumption and Mortality

Sex	Average Group Weight (g)	OPP Diet Consumed (g)
M (10)	274.95	482.1
F (10)	252.6	**0% Mortality**
Total (20)	Group Difference 22.35	

2. **45810710** J. Baroch. 2002. Norway Rat (*Rattus norvegicus*) Anticoagulant Dry Bait Laboratory Test Using LX-125 Bromadiolone Bait Pellets, Formula Number 403: Three-Day Test. Genesis Laboratories, Inc. Unpublished Report. Study #01031. 87pp.

DISCUSSION: This study was conducted to determine the efficacy of a pelleted bait formulated to be 0.005% bromadiolone for control of male and female Wistar albino rats from Harlan Sprague Dawley, Inc. in Indianapolis, Indiana in a three-day feeding test.

Rats arrived at the test facility October 22, 2001. The testing began November 1, 2001. The study followed Subdivision G (Product Performance) Guideline 96-10: Commensal Rodenticides, and the OPP guideline 1.203 (Standard Norway Rat/Roof Rat Anticoagulant Dry Bait Laboratory Test). The rats were presented with 85 g of the pelleted bait for three days. All forty rats (100%) died (Replicate I and Replicate II) and no control animals died.

This test was not run for 15 days as recommended in the OPP guideline 1.203, 7.1, with a 5 day post treatment observation, OPP guideline 1.203, 8.1. This study presented an anticoagulant pelleted bait to rats for 3 days (which there are no 3-day OPP test guidelines for a 3-day anticoagulant study).

In Appendix D7, Test Substance Accountability (page 85), the bromadiolone bait was formulated at Genesis Laboratory on October 11, 2001, and pelletized at Uniscope, Inc. Johnstown, Colorado, on October 12, 2001. The Genesis Laboratory log number was recorded as a reference number to the bait ("01-TS-38"). The OPP rat and mouse challenge diet formulation is referenced as an SOP.

Bait acceptance for the two treated groups combined was 56.5%. Approximately 85 g of pellets were issued to each rat. The label specifies 128 g (3 packets) to 425 g (10 packets) be placed uninterrupted for 10 days. Paper plates were placed beneath the feeding area of the rats to catch any spilled bait or challenge diet. There was no discussion about weighing back the spillage, just that it was figured into the equation. Since this was a 3-day test, there may be issues surrounding

reissuing the dishes back to the animals if previous practices by this lab were followed and the spillage was added back to the reissued test dish. The use of glass feeders is also questionable since the guidelines call for metal or ceramic feeders designed to the rats may not nestle or wallow in the diet. A stainless steel automatic watering systems was used instead of the gravity fed or open cup waterers as specified in the (OPP guidelines 1.203,6.2).

The guidelines for the test facility specify the temperature should range from 20 to 25 °C and the humidity should be between 50 and 55 % (OPP guideline 1.203, 5.1). The temperature for this test ranged from 19 to 26 °C pre-test and 18 to 26 °C during the test. The humidity ranged from 32 to 74 % pre-test and 24 to 71% during the test period. More consistency should be sought when conducting these laboratory tests.

The difference between the average pretest weights for the male and female rats should be within 50 grams and the average difference between the male and female weights pretest for this group was 4.6 grams. The males in the test weighed an average of_ = 227.6 grams and the females averaged _ = 232.2 grams.

Mortality in both treated groups was 100% for anticoagulant bait. The control group did not experience mortality. Results of the rat test are summarized below:

Table 1. Rep I - Rats on Pelleted Bromadiolone Bait

Pretest Weights **Bait 3-Day Test-Consumption and Mortality**

Sex	Average Group Weight (g)	OPP Diet Consumed (g)	Pelleted Bait Consumed (g)	Total Bait Consumption (g)
M (10)	245.46	774.7	967.5	1742.2
F (10)	240.95	**100% Mortality**		Percent **Pelleted Bait** Consumed **55.5%**
Total (20)	Group Difference 4.51			

Table 2. Rep II - Rats on Pelleted Bromadiolone Bait

Pretest Weights **Bait 3-Day Test-Consumption and Mortality**

Sex	Average Group Weight (g)	OPP Diet Consumed (g)	Pelleted Bait Consumed (g)	Total Bait Consumption (g)
M (10)	231.36	710.0	964.3	1674.3
F (10)	224.16	**100% Mortality**		Percent **Pelleted Bait** Consumed **57.6%**
Total (20)	Group Difference 7.2			

Table 3. Test III-Rats on OPP Challenge Diet
Pretest Weights Bait Consumption and Mortality

Sex	Average Group Weight (g)	OPP Diet Consumed (g)
M (10)	228.8	1501.8
F (10)	238.4	**0% Mortality**
Total (20)	Group Difference 9.6	

3. **45810711** J. Baroch. 2002. House Mouse (*Mus musculus*) Acute Dry Bait Laboratory Test Using LX-125 Bromadiolone Bait Pellets, Formula Number 403: One-Day Test. Genesis Laboratories, Inc. Unpublished Report. Study #01032. 73pp.

DISCUSSION: This study was conducted at Genesis Laboratories, Inc. in Wellington, Colorado, to determine the efficacy of a pelleted bait formulated to be 0.005% bromadiolone for control of male and female house mice from Harlan Sprague Dawley, Inc. in Indianapolis, Indiana, in a one-day feeding test.

One hundred and sixteen house mice arrived at Genesis Laboratories, Inc. on October 22, 2001. The mice were randomly assigned cages (972 cm^2) in same sex groups of 5 and were held in pretest holding acclimation for 7 days. The housing for the caged mice was less than half the recommended size according to the OPP guidelines 1.210, 3.1. The recommended size is 2000 cm^2. Only 2 shelters were provided as the cages were too small to place 3 shelters and test dishes, too, as noted in the Protocol Deviation # 1 (page 32), 4.1 and 5.1.

The mice were weighed pretest and then held for 3 more days of acclimation. The 1-day test per OPP guideline 1.210 began November 1, 2001, and ended November 15, 2001. The difference between the average weight of the female house mice (21.2 g) compared to the average weight of the male house mice (25.8 g) pretest was 4.6 g, an acceptable margin (5 g). The mouse groups were fed "at least 100 grams of test substance or challenge diet in each cup" (page 11 of 73).

In Appendix D7, Test Substance Accountability (page 69), the bromadiolone bait was formulated at Genesis Laboratory on October 11, 2001, and pelletized at Uniscope, Inc. Johnstown, Colorado, on October 12, 2001. The Genesis Laboratory log number was recorded as a reference number to the bait ("01-TS-38"). The OPP rat and mouse challenge diet formulation is referenced as an SOP.

The test room temperature is to be within 20 to 25 °C (OPP guideline 1.210) and the actual temperature ranged from 18 to 27 °C during the pretest holding and testing. The range in temperature is acceptable. The guidelines also specify the humidity in the test room to range between 50 and 55 % relative humidity. The

humidity recorded in the test room at Genesis Laboratories, Inc. during the acclimation period was 22 to 76 %. The humidity during the test was 22 to 68% and no raw data was presented to show the daily recording data. Some form of regulated humidification must be made available for use in these test rooms.

Water must be available to each animal at all times. Glass water bottles equipped with ball-type watering tubes are recommended. Gravity fed automatic or open-cup type waterers are not recommended (OPP guideline 1.210, 6.2). Glass water bottles with sipper tubes were used for this test. It is not known if the sipper tubes had a ball-type device.

OPP guidelines 1.210, 6.3 states that "Containers must be identical in size and type and must be placed equidistant from the sides of the cage and equidistant from the rodent's point of access to water." The rat and mouse challenge dishes in this test had "Food followers" placed on top to help control spillage. This may explain why the mice ate more of the pelleted bait than the rat and mouse challenge bait. They had no barrier on the pellets and limited access to the challenge diet. This was a 1-day test and the test dishes were rotated after 12 hours.

The OPP guidelines I.210, 8.1 states that "For "single-feeding" tests of anticoagulant baits, the post-exposure observation period must be at least 10 days." The protocol stated on page 8 (26 of 73) that "If signs of anticoagulant poisoning are evident on day 10 of the post-test observation, the test will be extended until symptoms are no longer observed or day 21, whichever comes first." In the Protocol Deviation (page 32 of 73), the explanation for extending the post-test observation was because the minimum mortality in treated groups had been exceeded and the surviving treated mice showed no adverse symptoms of test substance exposure.

Bait acceptance for the two treated groups combined was 29.8 %. For this test to be acceptable, at least 90 % of the test subjects must die during the bait exposure and post exposu

re observation periods. Mortality was 92.5 %.

Results of the mouse test is summarized below:

Table 1. REP I - Mice on OPP Challenge Diet and Pelleted Bromadiolone Bait - 1-Day Pretest Weights Test-Consumption and Mortality

Sex	Average Group Weight (g)	OPP Diet Consumed (g)	Pelleted Bait Consumed (g)	Total Pelleted Bait Consumption (g)
M (10)	25.09	34.3	15.9	50.2
F (10)	21.03	**90% Mortality**		Percent Pelleted Consumed **32%**
Total (20)	Group Difference 4.06			

Table 2. REP II - Mice on OPP Challenge Diet and Pelleted Bromadiolone Bait - 1-Day Pretest Weights Test-Consumption and Mortality

Sex	Average Group Weight (g)	OPP Diet Consumed (g)	Pelleted Bait Consumed (g)	Total Pelleted Bait Consumption (g)
M (10)	26.0	66.2	25.7	91.9
F (10)	21.28	**95% Mortality**		Percent Pelleted Consumed **28 %**
Total (20)	Group Difference 4.72			

Table 3. Mice on Control Bait
Pretest Weights Bait Consumption and Mortality

Sex	Average Group Weight (g)	OPP Diet Consumed (g)
M (10)	26.3	75.5
F (10)	21.4	**0 % Mortality**
Total (20)	Group Difference 4.9	

4. **4.45810712** J. Baroch. 2002. House Mouse (*Mus musculus*) Acute Dry Bait Laboratory Test Using LX-125 Bromadiolone Bait Pellets, Formula Number 403: Three-Day Test. Genesis Laboratories, Inc. Unpublished Report. Study #01033. 77pp.

DISCUSSION: This study was conducted at Genesis Laboratories, Inc. in Wellington, Colorado, to determine the efficacy of a 0.005% bromadiolone pelleted bait formulated for control of male and female house mice from Harlan Sprague Dawley, Inc. in Indianapolis, Indiana, in a three-day feeding test.

In the introduction to this study, a confusing statement was made in the first sentence: "The purpose of this study was to investigate the laboratory effectiveness of LX-125 Bromadiolone Bait Pellet, containing 50 ppm bromadiolone, Formula #210;". The mention of another Formula #210 instead of or in addition to Formula # 403 is confusing.

The introduction also states that the OPP guideline 1.204: Standard House Mouse Anticoagulant Dry Bait Laboratory Test Method is being followed. This test was not run for 15 days as recommended in the OPP guideline 1.204, 7.1, with a 5 day post treatment observation, OPP guideline 1.204, 8.1. This deviation from the guideline makes this a marginally acceptable study. This study presented an anticoagulant pelleted bait to mice for 3 days (which there are no 3 day OPP test guidelines for a 3-day anticoagulant study). Also, OPP guidelines 1.214 were mentioned on page 11 of 77 as the specific reference for the lighting for the test. This may have been a typographical error.

Sixty-nine house mice arrived at Genesis Laboratories, Inc. on November 12, 2001. The mice were randomly assigned cages (972 cm^2) in same sex groups of 5 and were held in pretest holding acclimation for 7 days. The housing for the caged mice was less than half the recommended size according to the OPP guidelines 1.204, 3.1. The recommended size is 2000 cm^2.

The mice were weighed pretest (November 19,2001) and then held for 3 more days of acclimation. The difference between the average weight of the female house mice (21.33 g) compared to the average weight of the male house mice (25.04 g) pretest was 3.71 g, an acceptable margin (5 g or less).

In Appendix D7, Test Substance Accountability (page 73), the bromadiolone bait was formulated at Genesis Laboratory on October 11, 2001, and pelletized at Uniscope, Inc. Johnstown, Colorado, on October 12, 2001. The Genesis Laboratory log number was recorded as a reference number to the bait ("01-TS-38"). The OPP rat and mouse challenge diet formulation is referenced as an SOP.

The test room temperature is to be within 20 to 25 °C (OPP guideline 1.204) and were recorded daily with a digital thermometer/hygrometer from Fisher, Model 11-661-13. The actual temperature ranged from 19 to 27 °C during the pretest

holding and testing. The range in temperature is acceptable. The guidelines also specify the humidity in the test room to range between 50 and 55 % relative humidity. The humidity recorded in the test room at Genesis Laboratories, Inc. during the acclimation period was 31 to 68 %. The humidity during the test was 25 to 60%. No raw data was presented to show the daily recording data. This is not acceptable. Some form of regulated humidification must be made available for use in these test rooms.

The mouse groups were fed "at least 70 grams of test substance and at least 80 grams of challenge diet in the respective cups at all times during the three-day choice test." (page 11 of 77). The OPP guidelines 1.204, 6.3, states that "The food offered in each container should be equal and consistent throughout the test and must be a least 15 grams per container per animal per day." The mouse groups of 5 should have recieved a minimum of 75 grams of food in each cup. This is another deviation from the guidelines.

Water must be available to each animal at all times. Glass water bottles equipped with ball-type watering tubes are recommended. Gravity fed automatic or open-cup type waterers are not recommended (OPP guideline 1.204, 6.2). Glass water bottles with sipper tubes were used for this test. It is not known if the sipper tubes had a ball-type device.

There is no mention of drying the spillage before weighing it back or how the spillage was accounted for. Page 11 of 77 states that "Spilled diet was collected by placing a 9 inch diameter paper plate under each cup of each cage. In addition, paper towel was added below the paper plate as a secondary method of catchment. At each 24-hour interval, the cups were removed, spillage was retrieved, and consumption was weighed to the nearest 0.1 gram." More clarification is needed about this practice of collecting spillage at this laboratory to determine if it affects the consumption. Was the spillage added back to the cups? Was it weighed separately, the weight added to the calculations, and discarded? How was the spillage handled? This was a 3-day test and the test dishes were rotated after 24 hours.

Bait acceptance for the two treated groups combined was 32.6 %. For this test to be acceptable, at least 90 % of the test subjects must die during the bait

exposure and post exposure observation periods. Mortality was 100 %.

Results of the mouse test are summarized below:

Table 1. REP I - Mice on OPP Challenge Diet and Pelleted Bromadiolone Bait - 1-Day Pretest Weights Test-Consumption and Mortality

Sex	Average Group Weight (g)	OPP Diet Consumed (g)	Pelleted Bait Consumed (g)	Total Consumption (g)
M (10)	25.26	159.9	80.2	240.1
F (10)	20.77	**100% Mortality**		Percent Pelleted Consumed **33.4%**
Total (20)	Group Difference 4.49			

Table 2. REP II - Mice on OPP Challenge Diet and Pelleted Bromadiolone Bait - 1-Day Pretest Weights Test-Consumption and Mortality

Sex	Average Group Weight (g)	OPP Diet Consumed (g)	Pelleted Bait Consumed (g)	Total Consumption (g)
M (10)	25.28	162.7	75.8	238.5
F (10)	21.37	**100% Mortality**		Percent Pelleted Consumed **31.8 %**
Total (20)	Group Difference 3.91			

Pretest Weights

Table 3. Mice on Control Bait
Bait Consumption and Mortality

Sex	Average Group Weight (g)	OPP Diet Consumed (g)
M (10)	24.59	270.9
F (10)	21.85	**0 % Mortality**
Total (20)	Group Difference 4.9	

Efficacy Comments

1. Two of the tests (MRID 45810710 and 45810712) were 15-Day tests that were abbreviated. Why were they not completed with a 5-Day posttest treatment after the last treated animal died?

2. Please provide a copy of SOP LR 4.02 so that we can see the method used to produce the challenge diet and provide the raw data notes for the process used for all four of the above tests.

3. The use of glass feeders is also questionable since the guidelines call for metal or ceramic feeders designed so the rats or mice may not nestle or wallow in the diet. A stainless steel automatic watering systems was used instead of the gravity fed waterers as specified in the OPP guidelines cited above. Did the sipper tubes used have a ball mechanism?

4. The OPP guidelines specify the temperature range from 20 to 25 °C and the humidity should be between 50 and 55 % in the test facility. In all of the tests, the temperature and humidity were not consistent and seemed out of control. More consistency should be sought when conducting these laboratory tests. A better form of regulated temperature and humidification must be made available for use in the test rooms.

5. No raw data was presented to show the daily temperature and humidity data. Please provide the raw data from the daily readings of temperature and humidity from the test rooms for each test from now on.

6. The housing for the caged mice was less than half the recommended size according to the OPP guidelines 1.210, 3.1, and 1.204, 3.1. The recommended size is 2000 cm^2.

7. It was not discussed why the three female mice that survived appeared on Day 10 in the 1-day mouse test (MRID 45810711, study 01032) and if they were healthy, why wasn't the test terminated then?

8. The rat and mouse challenge dishes in the mouse tests had "Food followers" placed on top to help control spillage. This is not consistent with the OPP guidelines section 6.3: "Containers must be identical in type and size..." Also, the mouse groups were fed "at least 70 grams of test substance and at least 80 grams of challenge diet in the respective cups at all times during the three-day choice test." (page 11 of 77). The OPP guidelines 1.204, 6.3, states that "The food offered in each container should be equal and consistent throughout the test and must be a least 15 grams per container per animal per day." Please note that these deviations are marginally acceptable.

9. Please address the formula discrepancy and reference to formula # 210, in Volume 13, page 9 of 77 (MRID 45810712).

10. The introduction for MRID 45810712 states that OPP guideline 1.204: Standard House Mouse Anticoagulant Dry Bait Laboratory Test Method is being followed. This test was not run for 15 days as stated in the OPP guideline 1.204, 7.1, with a 5 day post treatment observation, OPP guideline 1.204, 8.1.

11. On page 11 of 77 of Volume 13,, the OPP guideline 1.214 is mentioned. There is some confusion as to using 1.204, 1.214, or both. Please clarify this discrepancy.

12. In the introduction to this study (MRID 45810712), a confusing statement was made in the first sentence: "The purpose of this study was to investigate the laboratory effectiveness of LX-125 Bromadiolone Bait Pellet, containing 50 ppm bromadiolone, Formula #210;". The mention of another Formula #210 instead of or in addition to Formula # 403 is confusing. Please claify the formula being used for this study.

13. Please clarify the practice of collecting spillage by giving a written description of the process. Was the spillage added back to the cups? Was it weighed separately, discarded, and the weight added to the calculations?

Conclusion(s): The studies reviewed are marginally acceptable if the requested information is acceptable. The deviations from the guidelines, ommission of critical raw data, and not conforming to guideline specifications make these studies substandard. If these unacceptable practices mentioned above are continued in the future, studies will be rejected.

Label Comments

1. On the front of the label, replace "Kills" in the third line with "Controls" in it's place.

2. In the **SELECTION OF TREATMENT AREAS** section: the phrase: "...in or beside burrows,..." suggests that this bait may be used in a field situation. Also, the following phrase is too vague and ambiguous and should be deleted: "...in corners and concealed places,..." This statement should read: "Generally, these areas are along walls by gnawed openings, in or beside burrows within 15 feet of a building or wall, between floors and walls, or in locations where rodents or their signs have been seen."